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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GRUNBERG, ANNE MARIE

ART UNIT	PAPER NUMBER
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1661

DATE MAILED: 10/03/2003

3

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,932

Applicant(s)

KONZAK ET AL.

Examiner

Anne Marie Grunberg

Art Unit

1661

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1661.

Applicant should proof the specification and claims for any spelling or grammatical errors. For instance, there appears to be a spelling error in claim 20 for "benzaminopurine" which apparently should be changed to --benzylaminopurine--.

Double Patenting

I. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-34 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6362393. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus 'wheat' anticipates the species 'plant'.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 7 and 36, and dependent claims 2-35, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 36 are indefinite in step (d) because it is unclear if only stressed microspores are isolated or only stressed and "contacted" microspores are isolated. As a result, it is unclear whether step (d) occurs before or after step (c).

Claims 1 and 36 are also incomplete because the steps do not result in the product specified by the preamble. The product specified in the preamble is a plant, however the last step in the claims produces a microspore. As a result, it is unclear exactly what Applicant is claiming.

Claim 7 is indefinite due to "at least 20% dilution" because it is unclear whether the medium is diluted by 20% (ie 0.8x) or whether the medium is diluted to at least 20% of its original strength (ie 0.2x).

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 36, and dependent claims 2-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to wheat, does not reasonably provide enablement for claims broadly drawn to all plant varieties. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only provides guidance for obtaining wheat plants produced from microspores. No guidance is provided regarding the production of any other plants from microspores. In contrast, the claims are broadly drawn to any plant variety.

However, by following the methodologies exemplified in the present specification, one skilled in the art would only have been able to produce wheat from microspores. In *Genentech Inc. V. Novo Nordisk A/S* (42 USPQ2d 1001), the U.S. Court of Appeals Federal Circuit states on page 1005 that

“[2] It is true, as Genentech argues, that a specification need not disclose what is well known in the art. *See, e.g., Hybritech Inc. V. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one

skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement....”

It is well known in the art that tissue culture conditions, media, and procedure differ depending on the type of plant, or even genotype. The specification does not teach how any other plant except for wheat can be obtained from the procedure set forth.

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to produce any type of plant from microspores.

This rejection may be obviated by inserting --wheat-- in front of “plant(s)” on lines 1 and 2 of claim 1 as well as on lines 1 and 2 of claim 36.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 35 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kaneko et al.

Claim 35 is drawn to genetically transformed plants.

Kaneko et al teaches genetically transformed plants (first sentence of the abstract). The growth process taught by Kaneko et al differs from the claimed growth process in that a sporophytic development inducer was not used to induce sporophytic development. However, the claimed method of producing transgenic plants from microspores using a sporophytic development inducer would not distinguish the transgenic plant itself from that taught by Kaneko et al. See In re Thorpe, 227 USPQ 964,966 (fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Thus, the claimed invention was clearly prima facie obvious as a whole to one of ordinary skill in the art, if not anticipated by Kaneko et al.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasha et al.

Claims 1-36 are drawn to a method of producing plants from microspores wherein microspores are selected at a developmental stage amenable to androgenic induction. The microspores are subjected to temperature stress and a sporophytic development inducer, after which they are isolated and cocultured with either ovary-conditioned medium or at least one live plant ovary. Microspores may also be starvation stressed and the media may contain an auxin, a cytokinin, or gibberellin. A cell spindle inhibiting agent may be used to induce diploidy. Microspores may also be genetically transformed.

Kasha et al is a review article summarizing the state of the art of anther and microspore culture in 1990. Kasha et al teach a method of producing plants from microspores comprising selecting plant material with microspores at a developmental stage amenable to androgenic induction (page 224, line 3 under "III. Microspore Culture"); subjecting the microspores to

temperature stress to obtain stressed microspores (page 224, halfway through the first paragraph under “III. Microspore Culture”; page 225, bottom of second paragraph; page 227, lines 3-6); contacting the microspores with an amount of a sporophytic development inducer effective to induce sporophytic development (page 227, bottom and middle of the first paragraph); isolating the microspores (page 224, lines 3-8 under “III. Microspore Culture”); and coculturing the isolated microspores with either ovary-conditioned medium or at least one live plant ovary (page 224, first sentence of the second paragraph under “III. Microspore Culture”; page 227, second paragraph). The microspores within the selected plant material are in the mid uninucleate to early binucleate stage of development (page 224, line 13 under “III. Microspore Culture”; page 225, line 8; page 225, first sentence in the second paragraph; page 226, first paragraph under “A. Pollen Embryogenesis”). Microspores can be subjected to temperature stress with either high or low temperatures (page 227, line 4). The sporophytic development inducer includes 2-chloroethylphosphonic acid or other chemical sterilants related to ethylene production (page 227, bottom of first paragraph). Auxins, such as 2,4-dichlorophenoxyacetic acid are widely used in tissue culture (page 219, 3rd paragraph). Genetic transformation is taught at page 225, first full paragraph.

Kasha et al do not teach starvation induced stress of the microspores, nor particular stress temperatures or particular duration of temperature shock. Kasha et al also do not teach an aqueous medium comprising an at least 20% dilution of NPB 98. Kasha et al do not teach the specific concentrations of sporophytic development inducer. Kasha et al also do not teach specific auxin concentrations, nor do they teach specific cytokinin or gibberellin concentrations. Kasha et al also do not teach contacting microspores with an effective amount of a cell spindle inhibiting agent, nor do Kasha et al specifically teach stressed microspores isolated by density centrifugation nor do they teach a solution of mannitol layered over a higher density solution of maltose. Kasha et al also do not teach a liquid medium NPB98 or NPB-99

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of producing plants from microspores as exemplified in the review article by Kasha et al. The state of the art is summarized for the year 1990. It is readily apparent that the various limitations were well known in the art. Particular temperatures for temperature stress applications, as well as time ranges, concentrations of auxins, cytokinins, gibberellins, media type and starvation procedures would have been an optimization of process parameters and would have depended upon the species and genotype. It was well known in the art at the time that a cell spindle inhibiting agent, such as colchicine, could have been used to ensure doubled haploids. Density centrifugation was also widely used in the art for separating microspores from other plant materials.

9. Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genovesi et al in view of Köhler et al.

Claims 1-36 are drawn to a method of producing plants from microspores wherein microspores are selected at a developmental stage amenable to androgenic induction. The microspores are subjected to temperature stress and a sporophytic development inducer, after which they are isolated and cocultured with either ovary-conditioned medium or at least one live plant ovary. Microspores may also be starvation stressed and the media may contain an auxin, a cytokinin, or gibberellin. A cell spindle inhibiting agent may be used to induce diploidy. Microspores may also be genetically transformed.

Genovesi et al teach a method of producing plants from microspores comprising selecting plant material with microspores at a developmental stage amenable to androgenic induction (column 4, lines 41-48, lines 60-63, for example); subjecting the microspores to temperature stress to obtain stressed microspores (column 4, lines 18-21, for example); contacting the microspores with an amount of a sporophytic development inducer effective to induce

sporophytic development (column 16, lines 50-59); and isolating the microspores (column 4, lines 25-27, for example). The microspores within the selected plant material are preferably in the mid uninucleate stage of development (column 4, lines 67-68, for example). Microspores are subjected to temperature stress in a range of temperatures (column 4, lines 20-21; column 5, lines 5-8; page 227, line 4). The sporophytic development inducer is generically described at column 16, lines 49-60. Glycine, described at page 13, line 18 of the specification as a sporophytic development inducer is described at column 16, line 63. Auxins and cytokinin usage (column 16, lines 19-47), such as 2,4-dichlorophenoxyacetic acid are widely used in tissue culture (page 219, 3rd paragraph). Genovesi et al teach contacting microspores with an effective amount of a cell spindle inhibiting agent (column 23, line 36, for example) and an effective amount of sporophytic development inducer (column 23, line 32, for instance). Additionally, at column 6, lines 1-40 teach various methods of microspore isolation.

Genovesi et al do not teach coculturing the isolated microspores with either ovary-conditioned medium or at least one live plant ovary. Genovesi et al also do not teach an aqueous medium comprising an at least 20% dilution of NPB 98.

Köhler et al teach the coculturing of isolated microspores with ovary-conditioned medium (page 181, summary, for example).

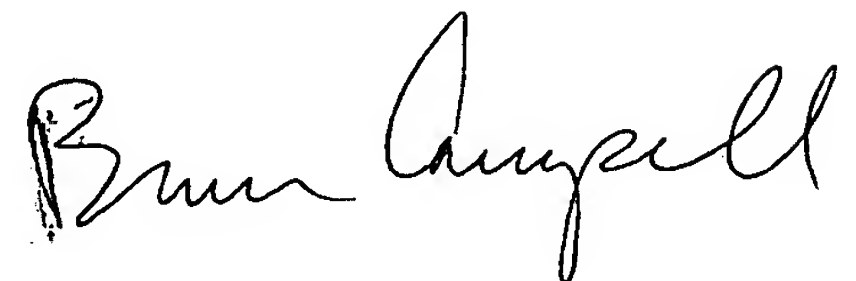
It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to utilize the method of producing plants from microspores as taught by Genovesi et al, and to modify that method by coculturing isolated microspores with ovary-conditioned medium given the advantages of increased regeneration and the guarantee of cell divisions of the isolated microspores as described by Köhler et al in the summary on page 181.

No claim is allowed.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Marie Grunberg whose telephone number is (703) 305-0805. The examiner can normally be reached Monday through Friday from 8:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (703) 308-4205. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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